

PATENT
Attorney Docket No. BSC-125C1
(1002/1481)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Gellman
APPLICATION NO.: Not yet assigned GROUP NO.: Not yet assigned
FILING DATE: Herewith EXAMINER: Not yet assigned
TITLE: Treating Urinary Incontinence

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicant hereby makes of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Per 37 C.F.R. 1.98(d), references A1-A134, B1-B26, and C1-C31 were previously submitted to, or cited by, the Office in U.S. Patent Application No. 09/992,359, which is relied upon in the present case for an earlier effective filing date under 35 U.S.C. 120, and, therefore, paper copies of these references are not enclosed. Should the Examiner require paper copies of some or all of these references, the Undersigned may be contacted at the telephone number listed below.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☒ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☐ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**

- ☐ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or
- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

STATEMENT

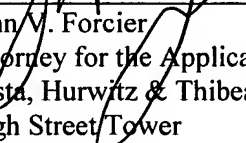
As required under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that:

- ☐ 1. Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application **not more than three months** prior to the filing of the Information Disclosure Statement; or
- ☐ 2. No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to **any individual** designated in 37 C.F.R. 1.56(c) **more than three months** prior to the filing of the Information Disclosure Statement.

Respectfully submitted,

Date: November 26, 2003
Reg. No. 42,545

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FORM PTO – 1449**INFORMATION DISCLOSURE STATEMENT****ATTORNEY DOCKET NO. BSC-125C1****APPLICANT:** Gellman**APPLICATION NO.:** Not yet assigned**FILING DATE:** Herewith**GROUP:** Not yet assigned**U.S. PATENT DOCUMENTS**

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A1	6,221,005 B1	04/24/01	Bruckner et al.			
	A2	6,110,101 US	8/29/2000	Tihon et al.			
	A3	6,102,921 US	8/15/2000	Zhu et al.			
	A4	6,099,547 US	8/8/2000	Gellman et al.			
	A5	6,090,116 US	6/18/2000	D'Aversa et al.			
	A6	6,068,591 US	05/30/00	Bruckner et al.			
	A7	6,059,801 US	05/09/2000	Samimi			
	A8	6,053,935US	04/25/2000	Brenneman et al.			
	A9	6,042,583 US	03/28/2000	Thompson et al.			
	A10	6,042,536 US	3/28/2000	Tihon et al.			
	A11	6,042,534 US	03/28/2000	Gellman et al.			
	A12	6,039,686 US	03/21/2000	Kovac			
	A13	5,997,554 US	12/7/99	Thompson			
	A14	5,934,283 US	08/10/99	Willem et al.			
	A15	5,922,026 US	07/13/99	Chin			
	A16	5,916,225 US	06/29/99	Kugel			
	A17	5,899,909 US	5/4/99	Claren et al.			
	A18	5,836,315 US	11/17/98	Benderev et al.			
	A19	5,836,314 US	11/17/98	Benderev et al.			
	A20	5,840,011 US	11/24/98	Landgrebe et al.			
	A21	5,836,961 US	11/17/98	Kieturakis et al.			
	A22	5,816,258 US	10/6/98	Jervis			
	A23	5,807,403 US	9/15/98	Beyar et al.			
	A24	5,769,864 US	6/23/98	Kugel			
EXAMINER					DATE		

FORM PTO – 1449 INFORMATION DISCLOSURE STATEMENT					ATTORNEY DOCKET NO. BSC-125C1 APPLICANT: Gellman APPLICATION NO.: Not yet assigned FILING DATE: Herewith GROUP: Not yet assigned		
	A25	5,766,221 US	6/16/98	Benderev et al.			
	A26	5,733,337 US	3/31/98	Carr, Jr. et al.			
	A27	5,707,647 US	01/13/98	Dunn et al.			
	A28	5,697,931 US	12/16/97	Thompson			
	A29	5,690,655 US	11/25/97	Hart et al.			
	A30	5,681,310 US	10/28/97	Yuan et al.			
	A31	5,645,915 US	07/08/97	Kranzler et al.			
	A32	5,645,849 US	07/08/97	Pruss et al.			
	A33	5,643,596 US	07/01/97	Pruss et al.			
	A34	5,643,288 US	7/1/97	Thompson			
	A35	5,641,566 US	06/24/97	Kranzler et al.			
	A36	5,641,502 US	06/24/97	Skalla et al.			
	A37	5,634,944 US	06/03/97	Magram			
	A38	5,634,931 US	06/03/97	Kugel			
	A39	5,620,012 US	4/15/97	Benderev et al.			
	A40	5,611,515 US	03/18/97	Benderev et al.			
	A41	5,591,163 US	1/7/97	Thompson			
	A42	5,582,188 US	12/10/96	Benderev et al.			
	A43	5,569,723 US	10/29/96	Titone et al.			
	A44	5,549,619 US	8/27/96	Peters et al.			
	A45	5,544,664 US	8/13/96	Benderev et al.			
	A46	5,527,342 US	06/18/96	Pietrzak et al.			
	A47	5,527,341 US	06/18/96	Gogolewski et al.			
	A48	5,507,796 US	04/16/96	Hasson			
	A49	5,474,543 US	12/12/95	McKay			
	A50	5,451,235 US	09/19/95	Lock et al.			
	A51	5,441,508 US	8/15/95	Gazielly			
	A52	5,437,603 US	8/1/95	Cerny et al.			
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FORM PTO – 1449					ATTORNEY DOCKET NO. BSC-125C1		
INFORMATION DISCLOSURE STATEMENT					APPLICANT: Gellman APPLICATION NO.: Not yet assigned FILING DATE: Herewith GROUP: Not yet assigned		
	A53	5,431,173 US	7/11/95	Chin			
	A54	5,425,984 US	06/20/95	Kennedy et al.			
	A55	5,425,737 US	6/20/95	Burbank et al.			
	A56	5,397,332 US	03/14/95	Kammerer et al.			
	A57	5,383,477 US	01/24/95	DeMatteis			
	A58	5,381,943 US	01/17/95	Allen et al.			
	A59	5,370,650 US	12/06/94	Tovey et al.			
	A60	5,368,602 US	11/29/94	de la Torre			
	A61	5,366,479 US	11/22/94	McGarry et al.			
	A62	5,366,460 US	11/22/94	Eberbach			
	A63	5,364,002 US	11/15/94	Green et al.			
	A64	5,362,294 US	11/8/94	Seitzinger			
	A65	5,356,064 US	10/18/94	Green et al.			
	A66	5,354,292 US	10/11/94	Braeuer et al.			
	A67	5,337,736 US	8/16/94	Reddy			
	A68	5,328,077 US	7/12/94	Lou			
	A69	5,304,220 US	04/19/94	Maginot			
	A70	5,292,328 US	03/08/94	Hain et al.			
	A71	5,290,217 US	3/1/94	Campos			
	A72	5,289,963 US	03/01/94	McGarry et al.			
	A73	5,263,969 US	11/23/93	Phillips			
	A74	5,258,000 US	11/02/93	Gianturco			
	A75	5,256,133 US	10/26/93	Spitz			
	A76	5,254,133 US	10/19/93	Seid			
	A77	5,195,542 US	3/23/93	Gazielly et al.			
	A78	5,178,630 US	1/12/93	Schmitt			
	A79	5,176,692 US	01/05/93	Wilk et al.			
	A80	5,149,329 US	9/22/92	Richardson			
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INFORMATION DISCLOSURE STATEMENT					APPLICANT: Gellman APPLICATION NO.: Not yet assigned FILING DATE: Herewith GROUP: Not yet assigned		
	A81	5,147,374 US	09/15/92	Fernandez			
	A82	5,122,155 US	06/16/92	Eberbach			
	A83	5,112,344 US	5/12/92	Petros			
	A84	5,064,434 US	11/12/91	Haber			
	A85	5,026,398 US	6/25/91	May			
	A86	5,019,032 US	5/28/91	Robertson			
	A87	5,013,292 US	5/7/91	Lemay			
	A88	5,012,822 US	5/7/91	Schwarz			
	A89	5,002,551 US	3/26/91	Linsky et al.			
	A90	4,997,434 US	3/5/91	Seedhom et al.			
	A91	4,986,831 US	01/22/91	King et al.			
	A92	4,973,300 US	11/27/90	Wright			
	A93	4,969,892 US	11/13/90	Burton et al.			
	A94	4,938,760 US	7/3/90	Burton et al.			
	A95	4,911,165 US	3/27/90	Lennard et al.			
	A96	4,905,692 US	3/6/90	More			
	A97	4,873,977 US	10/17/89	Avant et al.			
	A98	4,872,451 US	10/10/89	Moore et al.			
	A99	4,857,041 US	8/15/89	Annis et al.			
	A100	4,854,316 US	08/08/89	Davis			
	A101	4,838,884 US	06/13/89	Dumican et al.			
	A102	4,784,126 US	11/15/88	Hourahane			
	A103	4,769,038 US	7/6/88	Bendavid et al.			
	A104	4,741,330 US	5/3/88	Hayhurst			
	A105	4,655,221 US	04/07/87	Devereux			
	A106	4,652,264 US	3/24/87	Dumican			
	A107	4,633,873 US	1/6/87	Dumican et al.			
	A108	4,549,545 US	10/29/85	Levy			
EXAMINER					DATE		

FORM PTO – 1449				ATTORNEY DOCKET NO. BSC-125C1			
INFORMATION DISCLOSURE STATEMENT				APPLICANT: Gellman APPLICATION NO.: Not yet assigned FILING DATE: Herewith GROUP: Not yet assigned			
	A109	4,545,374 US	10/8/85	Jacobson			
	A110	4,520,821 US	6/4/85	Schmidt et al.			
	A111	4,452,245 US	6/5/84	Usher			
	A112	4,414,967 US	11/15/83	Shapiro			
	A113	4,409,974 US	10/18/83	Freedland			
	A114	4,400,833 US	8/30/83	Kurland			
	A115	4,347,847 US	09/07/82	Usher			
	A116	4,193,137 US	3/18/80	Heck			
	A117	4,175,557 US	11/27/79	Hung			
	A118	4,172,458 US	10/30/79	Pereyra			
	A119	4,085,756 US	4/25/78	Weaver			
	A120	3,823,705 US	7/16/74	Trimble			
	A121	3,744,495 US	7/10/73	Johnson			
	A122	3,705,575 US	12/12/72	Edwards			
	A123	3,666,750 US	5/30/72	Briskin et al.			
	A124	3,580,313 US	5/25/71	McKnight			
	A125	3,364,200 US	1/16/68	Ashton et al.			
	A126	3,124,136 US	3/10/64	Usher			
	A127	3,054,406 US	9/18/62	Usher			
	A128	2,671,444 US	3/9/54	Pease			
	A129	6,478,727B2	11/2002	Scetbon, Victor			
	A130	6,096,051	08/2000	Kortenbach et al.			
	A131	6,454,778 B2	09/2002	Kortenbach, Juergen A.			
	A132	6,423,080 B1	07/2002	Gellman et al.			
	A133	6,273,852	08/2001	Lehe et al.			
	A134	2002/0055748	05/2002	Gellman et al.			
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FORM PTO – 1449					ATTORNEY DOCKET NO. BSC-125C1				
INFORMATION DISCLOSURE STATEMENT					APPLICANT: Gellman APPLICATION NO.: Not yet assigned FILING DATE: Herewith GROUP: Not yet assigned				
FOREIGN PATENT DOCUMENTS									
EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B1	0 334 046 B1	06/18/97	EPO					Y
	B2	0 417 031 A2	03/13/91	EPO					Y
	B3	0 599 772 A1	06/01/94	EPO					Y
	B4	0 778 749 B1	12/27/2000	EPO					Y
	B5	2,268,690	01/19/94	GB					Y
	B6	6-114067	04/26/94	JP					N
	B7	503 271	03/01/96	SE				Y	Y
	B8	506 164	04/10/97	SE				Y	Y
	B9	88/01853	03/24/88	WO				Y	Y
	B10	92/16152	10/01/92	WO					Y
	B11	93/10715	06/10/93	WO					Y
	B12	93/10731	06/10/93	WO					Y
	B13	93/19678	10/14/93	WO					Y
	B14	94/19029	01/09/94	WO					Y
	B15	94/28799	12/22/94	WO					Y
	B16	96/06567	03/07/96	WO					Y
	B17	97/13465	04/17/97	WO					Y
	B18	97/30638	08/28/97	WO					Y
	B19	97/41792	11/13/97	WO					Y
	B20	97/43982	11/27/97	WO					Y
	B21	98/12971	04/02/98	WO					Y
	B22	98/35632	08/20/98	WO					Y
EXAMINER						DATE			

FORM PTO – 1449					ATTORNEY DOCKET NO. BSC-125C1				
INFORMATION DISCLOSURE STATEMENT					APPLICANT: Gellman APPLICATION NO.: Not yet assigned FILING DATE: Herewith GROUP: Not yet assigned				
	B23	00/74633 A2	12/14/00	WO					Y
	B24	43 23 578 A1	1/2/94	DE					N
	B25	2 268 690	1/19/94	GB					Y
	B26	98/35616	8/20/98	WO					Y
OTHER ART, JOURNAL ARTICLES, ETC.									
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)								
	C1	2001	Vasavada et al., Incisionless Pubovaginal Fascial Sling Using Transvaginal Bone Anchors for the Treatment of Stress Urinary Incontinence, Digital Urology Journal, July 24, 2001.						
	C2	2001	Urken, About our LifeCell Our Science, LifeCell, July 24, 2001.						
	C3	1997	Kovac: Pubic Bone Suburethral Stabilization Sling for Recurrent Urinary Incontinence, Obstetrics and Gynecology 89 :624-627 (1997).						
	C4	1997	Iglesia et al., "The Use of Mesh in Gynecologic Surgery", 8 :105-115 (1997).						
	C5	1996	Cruikshank: Anterior vaginal wall culdeplasty at vaginal hysterectomy to prevent posthysterectomy anterior vaginal wall prolapse, Am. J. Obstetrics and Gynecology 174 : 1863-1872 (1996).						
	C6	1996	Leach: Percutaneous Bladder Neck Suspension, Urol Clinics of N. Am. 23 : 511-516 (1996).						
	C7	1996	Petros et al., The Intravaginal Slingplasty Operation, a Minimally Invasive Technique for Cure of Urinary Incontinence in the Female, Aust. NZ J. Obstet. Gynaecol. 36 : 453-461 (1996).						
	C8	1995	Hoffman: Transvestibular Retropubic Bladder Neck Suspension: A pilot study, J. Reproductive Med. 40 : 181-184 (1995).						
	C9	1995	Trockman: Modified Pereyra Bladder Neck Suspension: 10-year mean follow-up using outcomes analysis in 125 patients, J. Urology 154 : 1841-1847 (1995).						
	C10	1995	Ulmsten: Intravaginal Slingplasty (IVS): An Ambulatory Surgical Procedure for Treatment of Female Urinary Incontinence Scand. J. Urol. Nephrol 29 : 75-82, (1995).						
	C11	1994	DeLancey, "Structural Support of the Urethra as it Relates to Stress Urinary Incontinence: The Hammock Hypothesis", <u>Am. J. Obstet Gynecol</u> , 170:1713-1723, 1994.						
	C12	1993	Blaivas et al., "Successful Pubovaginal Sling Surgery", <u>Contemporary Urology</u> , pp. 40-63, July 1993.						
EXAMINER								DATE	

FORM PTO – 1449 INFORMATION DISCLOSURE STATEMENT			ATTORNEY DOCKET NO. BSC-125C1 APPLICANT: Gellman APPLICATION NO.: Not yet assigned FILING DATE: Herewith GROUP: Not yet assigned
	C13	1991	Blaivas et al., "Pubovaginal Fascial Sling for the Treatment of Complicated Stress Urinary Incontinence", <u>The Journal of Urology</u> , Vol. 145, pp. 1214-1218, June 1991.
	C14	1990	Zimmern: A prospective evaluation of Four-Corner bladder neck suspension for Grade 11/111 Cystocele repair, <u>Neurol. and Urodynamics</u> 9: 231 (1990).
	C15	1988	Leach: Bone fixation technique for transvaginal needle suspension, <u>Urology</u> 31: 388-390 (1988).
	C16	1987	Gittes: No-incision pubovaginal suspension for stress incontinence, <u>J. Urology</u> 138: 568-570 (1987).
	C17	1987	Spencer: A comparison of Endoscopic suspension of the vesical neck with suprapubic vesicourethropey for treatment of stress urinary incontinence, <u>J. Urology</u> 137: 411-415 (1987).
	C18	1986	Bayer: A new approach to primary strengthening of colostomy with Marlex® Mesh to prevent paracolostomy hernia, <u>Surgery, Gynecology and Obstetrics</u> 163: 579-580 (1986).
	C19	1986	Stamey: "Endoscopic Suspension of the Vesical Neck", <u>Surgery of Female Incontinence</u> , 115-132, 1986.
	C20	1986	Zimmern: Transvaginal Closure of the Bladder Neck, <u>Seminars in Urology</u> 4: 30-32 (1986).
	C21	1985	Forneret: Cost-effective treatment of female stress urinary incontinence: modified pereyra bladder neck suspension, <u>Urology</u> 25: 365-367 (1985).
	C22	1983	Zacharin, "Abdominoperineal Urethral Suspension in the Management of Recurrent Stress Incontinence of Urine - a 15-year Experience", <u>Obstetrics & Gynecology</u> , Vol. 62, No. 5, (November 1983).
	C23	1983	Webster: "Female Urinary Incontinence," <u>Urologic Surgery</u> , J.B. Lippincott Company: Philadelphia, 665-679, 1983.
	C24	1982	Winter: Peripubic urethropey for urinary stress incontinence in women, <u>Urology</u> 20: 408-411 (1982).
	C25	1981	Richardson et al., "Treatment of Stress Urinary Incontinence Due to Paravaginal Fascial Defect", <u>Obstetrics & Gynecology</u> , Vol. 57, No. 3, (March 1981).
	C26	1980	Hancock: Transpubic suspension of the Bladder Neck for Urinary Incontinence, <u>J. Urology</u> 123: 667-668 (1980).
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	C27	1980	Stamey: Endoscopic Suspension of the Vesical Neck for Urinary Incontinence in Females: Report on 203 Consecutive patients, Ann. Surg. 192 : 465-471 (1980).	
	C28	1973	Nichols et al., "Identification of Pubourethral Ligaments and Their Role in Transvaginal Surgical Correction of Stress Incontinence", <u>Am. J. Obstet. Gynecol.</u> , Vol. 115, No. 1, January 1, 1973.	
	C29	1973	Stamey: Endoscopic Suspension of the vesical neck for urinary incontinence, Surgery, Gynecology and Obstetrics 136 : 547-554 (1973).	
	C30	1966	McKiel: Marshall-Marchetti Procedure: Modification, J. Urology 96 : 737-739 (1966).	
	C31		McGuire: The Sling Procedure for Urinary Stress Incontinence, Profiles in Urology - The Sling Procedure for Urinary Stress Incontinence.	
EXAMINER				DATE

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